CSPI Center for Science in the Public Interest
nonprofit publisher of *Nutrition Action Healthletter*

October 21, 2004

Lester Crawford, D.V.M., Ph.D., Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Re: Docket No. 87F-0179

Dear Dr. Crawford:

This is CSPI's 9th report to the FDA of adverse reactions to the food additive olestra. This report includes 290 adverse-reaction reports that CSPI received between April 9, 2003, to October 20, 2004, from consumers who believe that they or family members were adversely affected by olestra (Attachment I). CSPI has now submitted a total of 3,357 reports.

These new reports are similar to those that CSPI (and Procter and Gamble) submitted previously. To submit a report to CSPI, consumers have to work hard to find our web site and olestra adverse-reaction clearinghouse, which we have not been actively publicizing. Nevertheless, we continue to receive a steady stream of complaints.

The adverse-reaction reports continue to reflect all kinds of gastrointestinal misery. Most of the victims reported severe symptoms after eating just an ounce or two of chips. Thirty-four of the 290 victims sought medical attention, including 10 who went to the emergency room. Please see Attachment II for summaries of some of the victims' experiences.

The roughly 20,000 reports that have now been submitted to the FDA by CSPI and Procter and Gamble constitute more reports than for all other food additives in history combined. Still, one can be confident that the number of reports submitted represents only a small fraction of the number of people affected. In addition, Procter and Gamble is no longer sending reports to the FDA. We urge the FDA to ask Procter and Gamble to submit all reports from consumers who required medical care (and a summary of all other reports) since January, 2001. Even if the FDA is unconcerned that a food additive that it has approved causes adverse reactions, at the very least, as a health agency, it should track the number and kinds of reactions.

We also urge you to reinstate the olestra warning notice on packages of olestra-containing products. The need for a warning notice recently increased, because in September Frito-Lay changed the brand name for its olestra-based products from "WOW" to "Light" chips. Consumers who were trying to avoid olestra by avoiding WOW products are unwittingly buying

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

Light chips and sometimes getting sick. We urge FDA to require a prominent warning label on the fronts of packages stating that olestra can cause severe diarrhea or cramps. Your action on this issue is essential to protect toddlers, children, adults, and seniors from the pain, harm, embarrassment, and inconvenience that olestra is continuing to cause. Many consumers have undergone unnecessary pain and medical expenses because the label did not help them track down the cause of their symptoms.

Sincerely,

Michael F. Jacobson, Ph.D.
Executive Director

cc: Robert Brackett, Alan Rulis, Mary Ditto, William Hubbard, Dockets Management